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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,580

12/20/2007

Philip A. Beachy

JHU2010-1

2018

28213 7590 12/28/2009
DLA PIPER LLP (US)
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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,580	Applicant(s) BEACHY ET AL.	
	Examiner Sheela J. Huff	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-14 and 16-73 is/are pending in the application.
- 4a) Of the above claim(s) 23-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-14,16-22 and 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed on 10/13/09 has been considered.

Claims 1-3, 5-14, 16-73 are pending.

Claims 23-67 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-3, 5-14, 16-22 and 68-73 are currently under consideration.

Response to Arguments

Priority

Applicant argues that the Berman article discloses the same figures as in the instant application. In order for applicant to have priority to the provisional application, all the claim limitations must be present in the provisional application. The scope of the term antagonist is broader in the instant application than in the provisional application. The fact that the same figures are present in a journal article has no bearing on the provisional application.

Information Disclosure Statement

The IDS filed 10/13/09 has been considered and an initialed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 10-14, 16, 18 and 21-22 and 68-73 remain/are rejected under 35 U.S.C. 102(a) as being anticipated by Berman et al Nature vol. 425 p. 846 (10/23/03). This rejection is re-written in view of applicant's amendment.

This reference discloses the suppression of the Hh pathway in esophagus, stomach, biliary and pancreatic tumor cells by cyclopamine in vitro and in vivo. This reference also discloses that metastatic cancers can also be treated--see last line of article. These tumors are driven by endogenous expression of Hh ligand, such as sonic hedgehog and Indian hedgehog (see abstract and entire reference).

Response to applicant's arguments.

Applicant argues that this reference cannot be prior art in view of the priority date. The priority date remains 7/15/04 therefore the rejection remains.

Claims 1-3, 5-10 and 12-14, 16-21 and 68-73 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Ling et al US 2003/0022819. This rejection is re-written in view of applicant's amendment.

This reference discloses methods and reagents for the inhibition of undesired growth states that occur in cells with an active hedgehog signaling pathway. The reagents include hedgehog antagonists which include antibodies (including hedgehog antibodies), hedgehog proteins and small molecules (that read on steroidal alkaloid and derivatives thereof) and hedgehog mutants (see entire reference, [0137] +). The reference defines antagonist as a compound that inhibits activity of the hedgehog protein and inhibits ligand/hedgehog interactions ([0020]) (reads on claims 5-7 and 16). The antibodies are directed against sonic or Indian hedgehog ([0162] +). The tumors that can be treated by the reference include gastrointestinal tumors including metastatic cancers ([0558]) and Example 7 specifically shows the inhibition of the growth of colon cancer cells using anti-hedgehog. The compounds can be administered orally ([0565] +).

Response to applicant's arguments

Applicant argues that the reference discloses hedgehog signaling in angiogenesis and certain proliferative disorders and that behavior in one type of cell does not predict the behavior in another type of cell. The reference is directed to treating angiogenesis necessary for solid tumor metastasis (see paragraph 558). Thus the reference does disclose treatment in the same type of cell claimed by applicant.

Applicant argues that the no data is presented. The reference clearly discloses steps, compounds and methods for treating metastatic gastrointestinal tumors and the compounds used in the reference are the same as those claimed by applicant. In view

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of this explicit disclosure, one skilled in the art would immediately envisage the treatment.

Claims 1-3, 7, 10-14, 18 and 21-22 and 68-73 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/27135. This rejection is re-written in view of applicant's amendment.

This reference discloses molecules that counteract the phenotypic effects of unwanted activation of the hedgehog pathway. The molecules are steroidal alkaloid of other small molecules and specifically mentions cyclopamine (page 9, 32). The diseases to be treated include pancreatic cancer and gastrointestinal tumors such as stomach and intestine (page 59-61). Page 17 lines 8+ discloses the treatment in metastatic tumors.

Response to applicant's arguments

Applicant argues that the no data is presented. The reference clearly discloses steps, compounds and methods for treating metastatic gastrointestinal tumors and the compounds used in the reference are the same as those claimed by applicant. In view of this explicit disclosure, one skilled in the art would immediately envisage the treatment.

Claims 1-3, 5-14, 16-22 and 68-73 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Dudek et al US 2004/0060568 (filed 10/13/00). This rejection is re-written in view of applicant's amendment.

This reference discloses methods and reagents for the inhibition of undesired growth states (abnormal rate of proliferation --increased or decreased)([0092]) that occur in cells with an active hedgehog signaling pathway. The hedgehog antagonists are hedgehog antibodies, antisense nucleic acids, mutant hedgehog proteins and small molecules, such as cyclopamine ([0026], [0096], [0266] and [0168] and [0266] and entire reference). The use of the term hedgehog in the reference refers to sonic or indian hedgehog and therefore the antibodies are directed to sonic or Indian hedgehog. The cancer to be treated includes gastrointestinal tumors such as stomach intestine ([0571]) and example 8 specifically shows inhibition of colon cancer cell growth by anti-hedgehog antibodies. Administration can be oral ([0609]). The cancers to be treated also include metastatic cancers ([0081]).

Response to applicant's arguments

Applicant argues that the no data is presented. The reference clearly discloses steps, compounds and methods for treating metastatic gastrointestinal tumors and the compounds used in the reference are the same as those claimed by applicant. In view of this explicit disclosure, one skilled in the art would immediately envisage the treatment.

Applicant argues that the reference discloses hedgehog signaling in lung cancer and that behavior in one type of cell does not predict the behavior in another type of cell. As stated in the rejection, the cancer to be treated includes gastrointestinal tumors such as stomach intestine ([0571]) and the cancers include metastatic cancers ([0081]).

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Thus the reference does disclose treatment in the same type of cell claimed by applicant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday-Thursday 6am to 2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/
Primary Examiner
Art Unit 1643

sjh